Apex Surgical™

AUG 4 2000

510(K) SUMMARY

K000788

# Apex Modular™ Hip Stem

May 5, 2000


1. **Submitter:** Apex Surgical™, LLC
39 Taunton Green
Suite 202
Taunton, MA 02780

**Contact:** Edward J. Cheal, Ph.D.
Managing Director
(508) 884-9611 (voice)
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## 2. Device Name

| | |
|---|---|
| Proprietary Name: | Apex Modular™ Hip Stem |
| Common Name: | Hip prosthesis, uncemented |
| Classification Name: | Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis |
| Regulatory Class: | Class II per 21 CFR §888.3358 |

## 3. Intended Use

The Apex Modular Hip Stem is intended for use as the femoral component of a primary total hip replacement. This femoral hip stem is intended for uncemented fixation and single use implantation. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

## 4. Device Description

The Apex Modular Hip Stem consists of three modular components, with various sizes available for each component: the porous coated femoral stem, a modular neck that connects to the proximal end of the femoral stem, and a modular head that connects to the tapered trunion on the neck. This configuration allows the user to choose a combination of stem, neck, and head components to appropriately fit the anatomy of the patient. The various neck sizes allow for several length and lateral offset options for a given stem size. The modular heads are available in standard diameters so as to fit appropriate commercially available acetabular components of the surgeons' choosing. Several offset options are also available for the heads to allow further refinement of the lengths and offsets. The Apex Modular Hip Stem may be used in conjunction with the Link® SPII® Acetabular Cup for total hip arthroplasty.

The femoral stem and neck components are manufactured from titanium alloy, and the head components are manufactured from wrought cobalt chromium alloy, the same materials used to manufacture the predicate hip stems and heads, respectively. The proximal metaphyseal region of each size femoral stem is circumferentially coated with

unalloyed titanium applied by plasma spray. The alignment pin in the femoral stem is manufactured from wrought cobalt chromium alloy.

## 5. Predicate Device Comparison

Substantial equivalence is claimed to the S-ROM® Femoral Stem and the Biomet Modular Hip System. The table below compares the features and characteristics of the Apex Modular Hip Stem to these predicate devices.

| | **Apex Modular Hip Stem** | **S-ROM® Femoral Stem** (K913231, K934412, and K954935) | **Biomet Modular Hip System** (K921274) |
|---|---|---|---|
| **INTENDED USE** | | | |
| Primary and revision hip replacement, non-cemented use | Yes | Yes | Yes |
| **DESIGN** | | | |
| Plasma spray coating | Yes | No (sintered beads) | Yes |
| Proximal coating (only) | Yes | Yes | Yes |
| Modular head | Yes | Yes | Yes |
| Modular stem | Yes – modular neck | Yes – modular sleeve | Yes – modular distal stem |
| Straight distal stem | Yes | Yes | Yes |
| Fluted stem | Yes | Yes | Yes |
| Distal slot(s) | Yes – 1 or 2 slots | Yes – 1 slot | Yes – 1 slot |
| Proximal steps | Yes | Yes | No |
| **MATERIALS** | | | |
| Titanium alloy (Ti6Al4V) stem and neck | Yes | Yes | Yes |
| Cobalt chromium alloy head | Yes | Yes | Yes |
| Titanium porous coating | Yes – unalloyed | Yes – unalloyed | Yes – Ti6Al4V |

The two most significant differences between the Apex Modular hip stem and the two predicate hip stems relate to the design of the stem modularity (modular neck versus modular stem and sleeve for the S-ROM® or modular distal stem for the Biomet Modular) and the porous coating (plasma sprayed CP titanium versus sintered bead CP titanium for the S-ROM® or plasma sprayed titanium alloy for the Biomet Modular). Performance testing of the modular stem has been completed as per the relevant FDA guidance documents, including assembly testing of the neck-stem modular connection and fatigue testing of the assembled device. Performance testing of the plasma sprayed unalloyed (CP) titanium coating was completed as per the relevant FDA guidance documents with data in the referenced Device Master File.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

Edward J. Cheal, Ph.D.
Managing Director
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Taunton, Massachusetts 02780

Re: K000788
Trade Name: Apex Modular™ Hip Stem
Regulatory Class: II
Product Code: LPH
Dated: May 11, 2000
Received: May 12, 2000

Dear Dr. Cheal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

Device Name: **Apex Modular™ Hip Stem**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Vochmer

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number ~~D04~~ K000788

DPC

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR §801.109)

(Optional Format 1-2-96)